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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ROANE, AARON F	

ART UNIT	PAPER NUMBER
3769	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/812,476	HARRINGTON ET AL.	
	Examiner	Art Unit	
	Aaron Roane	3769	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 December 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,9-22,27-40 and 45-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,9-22,27-40 and 45-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/07/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 9, 10, 13, 17, 19-22, 27, 28, 31, 35, 37-40, 45, 46 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vancillie (U.S. Patent 5,095,917) in view of Tay et al. (U.S. Patent 5,810,810) and further in view of Zeluff (U.S. Patent 4,606,336).

Regarding claims 1-4, 9, 10, 19-22, 27, 28, 37-40, 45 and 46, Vancillie discloses a method of occluding the ovarian pathway of a female body said method comprising the steps of: applying a heating element in the form of a catheter-mounted high frequency bipolar electrode array (33) to a target segment of the pathway, and operating the heating element to heat the target segment in the pathway; limiting the heating of the target segment by applying power of 0.1 to 5 watts to the heating element for a period of at least about 5 seconds; and installing a plug into the target segment of the pathway, see col. 1-6, particularly col. 2, line 28 through col. 3, line 22 and figures 1-6. It should be further noted that the electrode array (33) is mounted on a catheter ("hollow tube" 30). Although it is well known in the art that high frequency includes radio Frequency (RF), Vancillie fails to explicitly recite that the high frequency bipolar electrode array is explicitly a Radio Frequency (RF) bipolar electrode array. Additionally, Vancillie fails to disclose

the claimed invention except for the plug being reticulated foam having a pore size of 40-200 microns or 1-20 microns. Vancillie disclose that the plug is an expandable, absorbable plug. However, Vancillie falls short of explicitly reciting the plug is a sponge or foam. Tay et al. disclose an electrode surgical medical device and teach "the frequency of the alternating electrical energy can be anywhere in the radio frequency range (10 kHz to 300 GHz). For medical reasons, the frequency should be above 25 kHz. For most applications, a high frequency energy range, generally 300 kHz to 1,000 kHz, may be used, with the frequency preferably being in the range of 300 kHz to 600 kHz, more preferably between 450 kHz and 550 kHz, and most preferably 500 kHz. In other applications, frequencies in the short wave range (10 MHz to 100 MHz), or in the microwave range (1 GHz to 300 GHz), will be more useful," see col. 11:57 – col. 12:10. Zeluff discloses an apparatus and method for sterilizing female reproductive organs and teaches providing a plug made of an expandable porous structure in order to promote ingrowth of fibroblast and create a hermetic seal at the uterotubal junction, see col. 3, line 28 through col. 4, line 23. Zeluff further discloses that the pore size is "on the order of 2 microns or greater," see col. 4, lines 56-64 and figures 1-12. It should be noted that an expandable porous material meets the claimed foam and reticulated foam structure. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Vancillie, as taught by Tay et al., to explicit use RF for the high frequency energy delivery in order to provide energy to tissue, as further taught by Zeluff, to make the plug from a porous foam having pore size "on the order of 2 microns or greater" in order to promote ingrowth of fibroblast and create a hermetic

seal at the uterotubal junction. **Additionally, with respect to the recited "inserting a catheter body including a retractable heating element in the form of a catheter-mounted RF electrode array into the ovarian pathway" and the recited "retracting the heating element and substantially simultaneously installing a plug into the target segment of the pathway while substantially maintaining the position of the catheter body relative to the target segment," it should be noted 1) that while the heating element (wounding element) is attached to the catheter it is therefore retractable and 2) the catheter along with its heating element (wounding element) are slightly retracted as the plug is pushed out into the targeted tissue site within the same medical procedure and therefore this is interpreted as substantially simultaneous as the target segment is the ovarian pathway and its surroundings and the catheter is still within the area it meets the newly recited subject mater as broadly interpreted by the examiner. Finally, the heating element and wounding element are interpreted as equivalents, as are the target segment and wounded segment.**

Regarding claims 13, 17, 31, 35, 49 and 53, Vancillie in view of Tay et al. in further view of Zeluff disclose the claimed invention of the foam plug in the form of an ePTFE plug, see Zeluff col. 4, lines 42-63.

Claims 11, 12, 15, 16, 29, 30, 33, 34, 47, 48, 51 and 52 rejected under 35 U.S.C. 103(a) as being unpatentable over Vancillie (U.S. Patent 5,095,917) in view of Tay et al. (U.S. Patent

5,810,810) and further in view of Zeluff (U.S. Patent 4,606,336) as applied to claims 9, 10, 27, 28, 45 and 46 above, and further in view of Barbacci (U.S. Patent 5,531,741).

Regarding claims 11, 12, 15, 16, 29, 30, 33, 34, 47, 48, 51 and 52, Vancillie in view of Tay et al. in further view of Zeluff disclose the use of silicone plugs for tubul occlusion, but fail to recite the silicone plug has a durometer of 1-200 Shore A and/or 60 Shore A. Barbacci discloses a uterine and/or fallopian tube stent and teach providing a stent made of silicone rubber having a durometer of 55 to 70 Shore A in order to provide comfort, see col. 7, lines 28-55, col. 8, line 66 through col. 9, line 11 and figures 1-22. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Vancillie in view of Tay et al. in further view of Zeluff, as taught by Barbacci, to provide a plug made of silicone having a durometer of 55 to 70 Shore A in order to provide comfort.

Claims 14, 18, 32, 36, 50 and 54 rejected under 35 U.S.C. 103(a) as being unpatentable over Vancillie (U.S. Patent 5,095,917) in view of Tay et al. (U.S. Patent 5,810,810) and further in view of Zeluff (U.S. Patent 4,606,336) as applied to claims 9, 10, 27, 28, 45 and 46 above, and further in view of Brundin (U.S. Patent 4,509,504).

Regarding claims 14, 18, 32, 36, 50 and 54, Vancillie in view of Tay et al. in further view of Zeluff disclose the claimed invention except for the plug made of an acrylic copolymer. Brundin discloses an apparatus and method for occluding body channels

including the female reproductive organs and teaches using an expandable plug (2) made of acrylic copolymers in order to provide a biocompatible seal, see col. 2, lines 18-41 and figures 1-6. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Vancillie in view of Tay et al. in further view of Zeluff, as taught by Brundin, to provide a plug made of an alternate material in the form of an acrylic copolymer in order to make a biocompatible seal.

Response to Arguments

Applicant's arguments filed 11/24/2009 have been fully considered but they are not persuasive.

Regarding Applicant's arguments/remarks with respect to the alleged reversibility/irreversibility conflict between Vancillie and Zeluff on page 10, 1st full paragraph through page 11, line 6, the fact that a plug partially formed from foam (taught by Zeluuf, reversible) is used in the method of Vancillie (irreversible) is moot as it is the porous material of Zeluff that allows and enhances fibroblast ingrowth of the surrounding tissue which both Vancillie and Zeluff desire and provide. That the feature of one reference cannot be physically incorporated into the primary reference does not render the combination of references improper. In re Nievelt, 482 F.2d 965, 179 USPQ 224 (CCPA 1973); In re Bozek, 416 F.2d 1385, 1390, 163 USPQ 545, 549-50 (CCPA 1969). The issue is whether the prior art, taken as a whole, would have rendered the claimed subject matter obvious. In re Young, 927 F.2d 588, 591, 18 USPQ2d 1089, 1091 (Fed. Cir. 1991); In re Keller, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). Additionally, the test for obviousness is not whether the features of a secondary

reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. In re Keller, 642 F. 2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). In this regard, a conclusion of obviousness may be based on common knowledge and common sense of the person of ordinary skill in the art without any specific hint or suggestion in a particular reference. In re Bozek, 416 F .2d 1385, 1390, 163 USPQ 545, 549 (CCPA 1969).

Finally as noted in the above rejections, with respect to the recited "inserting a catheter body including a retractable heating element in the form of a catheter-mounted RF electrode array into the ovarian pathway" and the recited "retracting the heating element and substantially simultaneously installing a plug into the target segment of the pathway while substantially maintaining the position of the catheter body relative to the target segment," it should be noted 1) that while the heating element (wounding element) is attached to the catheter it is therefore retractable and 2) the catheter along with its heating element (wounding element) are slightly retracted as the plug is pushed out into the targeted tissue site within the same medical procedure and therefore this is interpreted as substantially simultaneous as the target segment is the ovarian pathway and its surroundings and the catheter is still within the area it meets the newly recited subject mater as broadly interpreted by the examiner. Finally, the heating element and wounding element are interpreted as equivalents, as are the target segment and wounded segment.

The Applicant is invited to request an interview to discuss suggestions to find an acceptable conclusion of the prosecution for all parties.

This action is made FINAL.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron Roane whose telephone number is (571) 272-4771. The examiner can normally be reached on Monday-Thursday 8:30AM-7PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Johnson can be reached on (571) 272-4768. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Aaron Roane/
Examiner, Art Unit 3769

/Henry M. Johnson, III/
Supervisory Patent Examiner, Art Unit 3769